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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/898,425 | 07/03/2001 | Roberto Valducci | 242/9-1568 | 1890 |

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 09/25/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/898,425

Applicant(s)

ROBERTO VALDUCCI

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-22 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Examiner acknowledges receipt of IDS filed 05/30/02, request for extension of time filed 07/08/02, non-compliant amendment B filed 07/08/02 and amendment C filed 08/21/02.

Applicant is reminded that the amendment filed 07/08/02 was non-complaint and was therefore not entered.

It appears that claim 1 was cancelled but applicant failed to indicate ---cancel claim 1--- in the amendment filed on 08/21/02. Also, no argument to the pending office action was presented in the paper filed 08/21/02. Furthermore, the amendment to page 3, lines 21-26 of the specification is not presented in the amendment filed 08/21/02.

It is suggested that applicant formerly and appropriately file those amendments in response to this action. Applicant is encouraged to communicate with the examiner by telephone if clarification is needed.

Since applicant failed to formerly respond to the outstanding office action, the action is repeated below.

Claim Rejections - 35 USC § 112

1. The amendment to the claims appears to overcome the rejection under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, and thus, said rejection is withdrawn.

Claim Rejections - 35 USC § 102

2. Claims 1-6, 8, 15, 18, 19 and 21 remain rejected under 35 U.S.C. 102(e) as being anticipated by Watts (US 6,228,396).

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Watts discloses a colonic drug delivery composition (abstract). The composition comprises active agents such as hydrocortisone, budenonide, cisapride, anticholinergics, opioids and calcium channel blockers and the composition can also be used to deliver antiviral agents for HIV (column 4, lines 32-61). The formulation delivered either as tablets or starch capsules are coated and the coating composition is enteric (pH sensitive) where the coating composition is selected from cellulose acetate trimellitate, hydroxypropylmethyl cellulose phthalate, polyvinyl acetate phthalate and shellac (column 1, lines 48-67, column 2, lines 4-8, lines 32-64 and column 3, lines 12-20). Watts suggests optimizing the coating composition to maximize disintegration (column 2, lines 61-64). Mesalazine tablets coated with EUDRAGIT are known and dissolve above pH 6:00. Claims are broadly directed to active agents and polymer and a composition meeting the limitations of claim 1 would have the release profile recited in claim 3. Therefore, Watts anticipates the claims.

3. Claims 1-3, 5, 6, 8, 15, 16, 18, 19 and 21 remain rejected under 35 U.S.C. 102(e) as being anticipated by Yajima et al. (US 5,972,373).

Yajima teaches a composition comprising macrolide antibiotics (column 2, lines 38-48) and polymers (column 2, lines 55-57). The composition is formulated into granules, powders, capsules, tablets and dry syrups (column 3, lines 15-18) and these formulations are enteric coated (column 3, line 48). The composition further comprises excipients (mannitol, carboxymethylcellulose), disintegrants (starch and crystalline cellulose), binders (hydroxypropylmethyl cellulose and propyleneglycol alginate), lubricants (stearic acid) and antioxidant (BHT, BHA and alpha-tocopherol and citric acid). See column 3, lines 1-48). The coating agent includes hydroxypropylmethyl cellulose phthalate, hydroxypropylmethyl cellulose

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acetate succinate and the composition further comprises dyestuff and titanium oxide (column 3, lines 58 and 59). Claims are broadly directed to active agents and polymer and a composition meeting the limitations of claim 1 would have the release profile recited in claim 3. Thus, Yajima anticipates the claims.

Claim Rejections - 35 USC § 103

4. Claims 1-16 and 18-22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Watts (US 6,228,396) in view of Isizuka et al. (US 67,160,017) or Ishizuka et al. (US 6,160,017) in view of Watts (US 6,228,396).

Watts is discussed above. Watts does not teach a multilayer-tablet formulation but discloses that the formulation can be used for treating ulcerous colitis and/or Crohn's disease.

However, Ishizuka discloses a composition comprising conagenin or a pharmaceutically acceptable salt thereof (abstract). The composition further comprises carriers and some of the excipients listed are lactose, starch, crystalline cellulose, silicic acid, shellac, methylcellulose, polyvinylpyrrolidone, stearic acid, and polyethylene glycol (column 3, lines 45-62). The composition is formulated into multilayer-coated tablets and the tablets are enteric coated, sugar coated or gelatin coated (column 3, lines 63-67). This composition is used for treating ulcerous colitis and/or Crohn's disease.

Watts and Ishizuka separately teach separate compositions for treating ulcerous colitis and/or Crohn's disease. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205

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USPQ 1069, 1072 (CCPA 1980). Therefore, it is prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Watts in the manner disclosed by Ishizuka or Ishizuka in the manner taught by Watts. Since both prior art references teach formulations for treating ulcerative colitis and/or Crohn's disease, one having ordinary skill in the art would have been motivated to prepare a multi layered tablet formulation comprising, active agents such as hydrocortisone, mesalazine, budenonide, cisapride, anticholinergics, opioids, conagenin and calcium channel blockers, coating composition selected from cellulose acetate trimellitate, hydroxypropylmethyl cellulose phthalate, polyvinyl acetate phthalate and shellac and stearic acid to provide a third composition from the combined teachings of Watts and Ishizuka to treat ulcerous colitis and/or Crohn's disease. The expected result is a multi layered tablet formulation comprising active agents, polymers or mixtures of polymer and carrier.

Discussion: Applicant broadly claims an oral formulation that comprises an active agent combined with different polymers or mixtures of polymers where each polymer or mixtures of the polymers are soluble at starting pH's that are different from each other polymer or mixtures of the polymers. Any active agent in combination with any polymers meets the limitations of the claims as presented and said oral formulation would inherently have the properties recited in the claims. The prior art of record teaches active agents in combination with polymers.

5. Claim 17 remains objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, because the prior art of record does not teach diethylphthalate.

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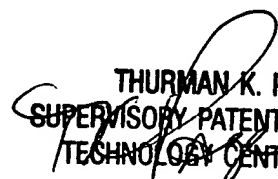
6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification including the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
September 23, 2002


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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